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SFATA's Proposed Alternative Approaches to FDA Implementation of the Deeming Regulations to Vapor Products
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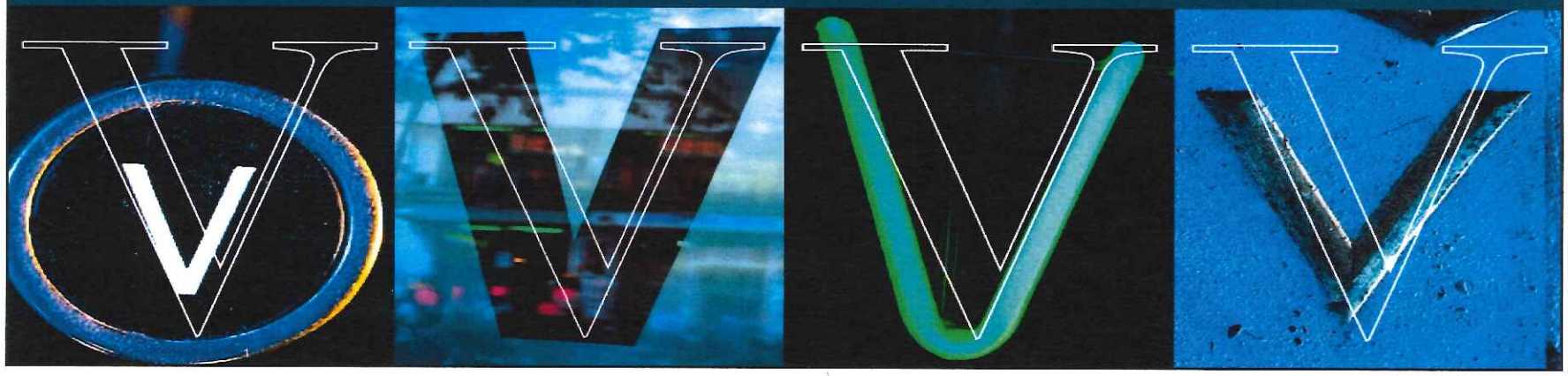

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The Problems

- FSPTCA (the "Act") was neither intended nor written to contemplate or accommodate newer technologies such as electronic cigarettes or other vapor products ("e-cigs").
- Grandfather/predicate product eligibility date (Feb. 15, 2007) was based on traditional tobacco products.
- No post-deeming "transition period" for SE explicitly built into the Act like there was for initially regulated products.
- With the Feb. '07 date and current FDA guidance, SE is practically unworkable, and NTP pathway is unnecessarily burdensome for e-cigs.
- With full regulation under an overly literal interpretation of the Act, FDA could essentially ban all or nearly all e-cigs; thereby, effectively removing the only true harm reduction technology available to smokers.
  - Potential to quash a potentially much safer alternative to smoking.
    - FDA-approved drugs have been ineffective at achieving long term smoking cessation.

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The Solutions

- *See* SFATA comments to proposed deeming rule (attached).
- Challenge FDA on the jurisdictional issue, i.e., is an e-cig a "tobacco product" under the Act?
  - Litigation on this and other points likely if Vapor Products are in final deeming rule.
- In case FDA is determined to have the jurisdiction by a court to regulate Vapor Products as tobacco products under the Act (and is successful), comments in the docket offer reasonable solutions to allow an orderly transition to a reasonable level of regulation that could be implemented as part of the deeming regulations.

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Jurisdiction

- The term "tobacco product" means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).
  - Even if the nicotine in an e-cig was extracted from tobacco, this connection is legally tenuous at best
    - The Act would not apply to non-nicotine vapor products nor vapor products that derive their nicotine content from a source other than tobacco.
- Congressional findings focus on harms relating to traditional tobacco products and regulation of the "tobacco industry."
  - Congress simply did not consider Vapor Products.
- A close reading of *Sottera* suggests that this case does not definitively establish that e-cigs are tobacco products, but only that they are not drugs/devices.

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Regulatory Solutions if FDA Deems Vapor Products to be Tobacco Products and the Courts Agree

- If FDA regulates e-cigs under the existing Act, it need not be an "all or nothing" approach.
- Regardless of whether FDA has the authority under the Act to simply "change" the grandfather date, there are various ways that FDA can provide for an orderly transition to a regulatory structure that fits Vapor products without unduly burdening industry and depriving consumers of their preferred product choices and to reduce their risk of harm associated with smoking traditional tobacco products:
  - Investigational Use Exemption
  - Partial deeming
  - Enforcement discretion
  - "Efficient enforcement" regulatory authority
  - Extended compliance dates
  - Use of a tobacco product "standard" and/or streamlined clearance process

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What is a "Reasonable" Level of Regulation?

- Reasonable minds can (and do) differ greatly on how much regulation is appropriate for Vapor products.
- Possibilities include:
  - Adulteration, GMP, misbranding
  - Registration and listing
  - Ingredient and HPHC reporting
  - Appropriately tailored health warnings
  - 18 years as minimum age for purchase

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Investigational Use

- FDA "may exempt tobacco products intended for investigational use from the provisions of this chapter under such conditions as the Secretary may by regulation prescribe." FDCA § 910(g).
  - This can be an extremely flexible and powerful tool.
- FDA has the ability to consider all Vapor products to be "investigational use" products as well as provide a streamlined reporting mechanism to obtain "investigational use" status?
- FDA could then use its "under such conditions" authority to gather information such as described above under "reasonable" regulations.
  - Also allows time for the science to develop in areas such as population effects, harm reduction, ingredient safety, etc.
    - Given the failure of traditional treatment options, Vapor products may offer the best opportunity to reduce the risk of harm associated with smoking traditional tobacco products.
  - Encourages and allows industry to focus on optimizing product safety, rather than burdensome and pointless filings for FDA clearance.
- All of this is appropriately considered "investigational use," a term that is not defined by the Act and is left to FDA's inherent regulatory discretion.

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Partial Deeming

- "This chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter." FDCA § 901(b).
- If FDA has the power to deem Vapor products subject to the Act, it logically follows that it also inherently has the power to take the less drastic step of deeming e-cigs subject to specific portions of the Act.
- This is bolstered by FDA's power to exercise "enforcement discretion" and "to promulgate regulations for the efficient enforcement of" the Act under FDCA § 701(a).
- This too offers an opportunity to implement a "reasonable" set of regulations for e-cigs, including moving the grandfather date.

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Extended Compliance Dates

- Under its enforcement discretion and 701(a) authority, as well as the deeming provision, FDA has ample authority to extend compliance dates.
- More "reasonable" requirements, such as information gathering, can be implemented sooner
  - but FDA should delay compliance with any type of market clearance provision so that it has time to thoughtfully consider whether and how such a provision can be reasonably implemented.
    - At least 48 months from the date FDA implements any type of clearance procedure appropriately tailored to e-cigs.
    - Or, better yet, indefinitely.

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Tobacco Product Standards

- FDA "may adopt tobacco product standards . . . if [FDA] finds that a tobacco product standard is appropriate for the protection of the public health." FDCA § 907(a)(3)(A).
- Food for thought: FDA could establish, with input from industry, standards for Vapor products that help assure their safety.
  - Products that meet the standard would be considered to be cleared.
    - Note: the "appropriate for the protection of the public health" standard for tobacco product standards is the same language used for clearance of NTP applications.
  - Possible reporting requirement to demonstrate compliance?
  - Investigational use exemption for products not meeting the standard?